

REMARKS

By way of the present amendment, claims 31, 33-38 and 75-96 are pending. Claims 31, 36, 93, and 94 have been amended without prejudice. Claims 95-98 have been newly added. Support for the claim amendments can be found throughout the specification and the claims as originally filed, for example, see the present specification at page 11, lines 1-2. Additional support for such amendments will be apparent to one of skill in the art. No new matter has been added by way of the present amendment.

Rejection under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 31, 33-38 and 75-94 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabling one of skill in the art to make and/or use the invention. This rejection is respectfully traversed for at least the reasons which follow.

Initially, it is submitted that the Examiner has not met the evidentiary burden to impose an enablement rejection for failure to enable one of skill to use the invention. A specification that discloses how to make and use a claimed invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented “must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein.” *In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995) (*quoting In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (CCPA. 1971) (emphasis in original)).

The U.S. Patent and Trademark Office (“Office”) acknowledges that the specification is enabled for transforming soybean cells with soybean derived sequences from the FAD2, FATB or delta-9 desaturase genes. *See Office Action* at page 3. However, the Office asserts that the specification is only enabled for suppression of soybean FAD2 and FAD3 genes and increased expression of delta-9 desaturase. While Applicants disagree that the specification is only enabled for suppressing soybean sequences, the claims have been amended to facilitate prosecution. However, Applicants dispute that one skilled in the art would not be able to increase expression of any delta-9 desaturase gene other than soybean. A person of ordinary skill in the art has access to extensive knowledge for increasing expression of a protein in a

soybean seed, *e.g.*, various mechanisms for creating a diverse collection of expression constructs. Performing routine and well-known steps, such as creating and transforming constructs into soybean seeds for expression assays, cannot create undue experimentation, even if it is laborious. *See In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (CCPA 1976).

The Office alleges that the metabolic engineering of fatty acids in plants is unpredictable and points to a recent review article, Singh *et al.* (2005 Current Opinion in Plant Biology 8:197-203) ("Singh"). *Office Action* at page 3. More particularly, the Office quotes Singh at page 199, "The choice of plant species, enzymatic pathway, and transgene source all appear to strongly influence the efficiency of LC-PUFA synthesis in transgenic plants." *Id.* However, Singh's definition of LC-PUFA is beyond the scope of the present invention. LC-PUFAs as defined by Singh are "normally obtained from marine sources such as microalgae and fish" and as "unusual fatty acids." Singh at page 197, first full paragraph and at page 200, last full paragraph. Moreover, Applicants' claims are not directed to efficiency of fatty acid production.

The Office cites Jaworski *et al.* (2003 Current Opinion in Plant Biology) to suggest that the genes of the claimed invention do not necessarily have the same function in all plant species. To facilitate prosecution, Applicants have amended the claims to recite soybean plant cells and suppression of soybean FAD2. As such, this issue is now moot.

Similarly, the present claim amendments should resolve the Office's concerns about unpredictability of expression levels as allegedly found in Colliver *et al.* (1997 Plant Mol. Biol. 35:509-522) and Stam *et al.* (1997 Annals of Botany 79:3-12). *See Office Action* at page 4. The Office proposes that expression levels vary using antisense and co-suppression methods, yet the working examples presented in the present specification provide evidence of steady suppression of soybean FAD2 and FATB genes in soybean plants.

Even assuming that the Office's generalization regarding the unpredictable state of the art is accepted, any conclusion that undue experimentation would be required is inconsistent with the considerable direction, guidance, and working examples provided by Applicants. As such, the Office has not provided sufficient evidence to cast doubt on the guidance provided in the specification. Rather, the Office has provided inapplicable generalizations regarding unpredictability in the art.

Rejection under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 31, 33-38 and 75-94 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not being described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time of filing. *Office Action* at page 5. The Office acknowledges that the specification describes transforming soybean cells with soybean derived sequences from the FAD2, FATB, or delta-9 desaturase genes. *See id.* While Applicants disagree that the specification only describes suppressing soybean sequences, the claims have been amended to facilitate prosecution.

Rejection under 35 U.S.C. § 103

Claims 31, 33-38, 75, 78-84, and 87-94 stand rejected under 35 U.S.C. § 103 as allegedly being obvious over Buhr *et al.* (2002 *The Plant Journal* 30:155-163) ("Buhr") in view of Thompson *et al.* (U.S. Patent No. 5,723,595) ("Thompson"). Applicants thank the Office for acknowledgement that claims 76-77 and 85-86 are free of the art. *See Office Action* at page 11.

Even when combined, the teachings of Buhr and Thompson do not teach or suggest the claimed invention. As acknowledged by the Office, Buhr does not teach or suggest increasing the endogenous expression of a delta-9 desaturase gene in addition to suppression of FAD2-1 and FatB, and Thompson fails to provide any teaching or suggestion of the combination either.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of skill in the art, to modify the reference or to combine reference teachings. Moreover, there must be a reasonable expectation of success. A teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Instead the Office is using the Applicant's specification as a hindsight guide to combine these references. Such an approach is not permissible. The Office has failed to establish a *prima facie* case of obviousness because the Office has not provided an adequate explanation of the suggestion or motivation to combine the teachings of Buhr with Thompson to teach the claimed invention merely stating that the motivation to combine these references is based on the

disclosure by Thompson in which there is a desire in the field to provide alternatives to current sources of highly saturated oil products. *See Office Action* at page 9.

But neither Buhr nor Thompson suggest increasing the endogenous expression of a delta-9 desaturase gene in addition to suppression of soybean FAD2-1 and FatB genes. The Office cites Thompson as providing motivation with the statement that “[d]epending on the intended oil use, various oil compositions are desired. For example, edible oil sources containing minimum possible amounts of saturates, palmitate (C16:0) and stearate (C18:0) saturated fatty acids, are desired for dietary reasons and alternatives to current sources of highly saturated oil products, such as tropical oils, are also needed.” *Id.* But there is no suggestion to create such an edible oil by combining an increase in the endogenous expression of delta-9 desaturase with suppression of soybean FAD2-1 and FatB genes.

Moreover, while the Office states that claims 78-83 and 87-92 recite “multiple design choices” for the claimed subject matter which are well known in the art, this is not the case as, for example, claims 75, 76, 84, 85, 95, 96, 97 and 98 recite the use of a FAD2 intron or fragment thereof. Nothing in either Buhr or Thompson discloses the use of a FAD2 intron or fragment thereof.

For the foregoing reasons, Applicants respectfully assert that the Office has failed to establish a *prima facie* case of obviousness over the combined teachings of Buhr and Thompson. Hence, the cited references taken alone or in combination do not teach or suggest the present invention. Therefore, Applicants respectfully request withdrawal of the rejection of claims 31, 33-38, 75, 78-84, and 87-94 under 35 U.S.C. § 103(a).

Double Patenting Rejection

Claims 31 and 33-38 stand provisionally rejected under the judicially created doctrine of obvious-type double patenting as allegedly being unpatentable over claims 31 and 33-38 of co-pending U.S. Application Serial No. 10/508,401.

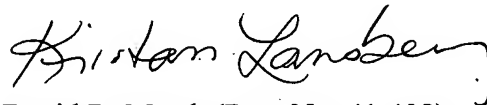
In order to facilitate prosecution, Applicants are willing to submit a Terminal Disclaimer in the present case with regard to U.S. Application Serial No. 10/508,401 or cancel those claims in U.S. Application Serial No. 10/508,401 upon an indication of allowable subject matter. Additionally, it is noted that the filing of a terminal disclaimer to obviate a rejection based on non-statutory double patenting is not an admission of the propriety of the rejection. *See, e.g.,*

Quad Environmental Technologies Corp. v. Union Sanitary District, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991) ("filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection.")

CONCLUSION

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding objection and rejections of the claims, and to pass this application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-5186 should any additional information be necessary for allowance.

Respectfully submitted,



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Date: November 3, 2006

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